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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,527	05/09/2001	Lydie Bougueleret	45.US2.PCT	8473

23557 7590 06/03/2003

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EXAMINER
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PAK, YONG D.

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/744,527

Applicant(s)

BOUGUELERET, LYDIE

Examiner

Yong Pak

Art Unit

1652

-- The MAILING DATE of this communication appears in the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 March 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,10,15,21,24-28,32 and 39-81 is/are pending in the application.
- 4a) Of the above claim(s) 1,10,15,21,24-28,32,39-42,80 and 81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 43-79 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1652

### **DETAILED ACTION**

The amendment filed on March 24, 2003, amending claim 43 and adding claims 69-81, has been entered.

Claims 1, 10, 15, 21, 24-28, 32 and 39-81 are pending.

### ***Election/Restrictions***

Newly submitted claims 80-81 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: a method of using the DNA of Invention I. Claims drawn to a method of producing GGPPS were grouped in Invention I because the claims recite host cells comprising DNA encoding said protein.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 80-81 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Further, claims 1, 10, 15, 21, 24-28, 32 and 39-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 69-76 and 78-79 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 69-76 and 78-79 are drawn to a composition comprising a contiguous span of SEQ ID NO:4 where in the contiguous span includes Phe at position 204, Cys at position 205, a Pro at position 225 and a Phe at position 295. Therefore, these claims are drawn to a genus of polypeptides, with any structure and from any source.

The specification does not contain any disclosure of the structure and function of all geranylgeranyl pyrophosphate synthetase (GGPPSASE) fragments or portions of SEQ ID NO:4. The genus of polypeptides that comprise these fragments and portions of GGPPSASE is a large variable genus with the potentiality of encoding many different proteins. Further, a description of less than 200 amino acids, which represent less than 66% of the whole structure of the whole structure of SEQ ID NO:4, amount to insufficient description of the structure of the polypeptides in this claim. Therefore, these claims are drawn to a large variable genus of DNA molecules encoding polypeptides having unknown activity or inactive variants with an insufficient limitation on structure. Therefore, many structurally and functionally unrelated polypeptides are

Art Unit: 1652

encompassed within the scope of these claims, including partial amino acid sequences.

The specification fails to describe any other representative species by any identifying characteristics or properties or the "functionality" of the polypeptides and fails to provide any structure: function correlation present in all members of the claimed genus.

Therefore, the specification is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Claims 69-76 and 78-79 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the GGPPSASE of SEQ ID NO:4, does not reasonably provide enablement for fragments of SEQ ID NO:4 of unknown structure and function. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, how to make the invention commensurate in scope with these claims.

Factors to be in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) considered in determining whether undue experimentation is required, are summarized the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are drawn to polypeptides comprising fragment or portions of SEQ ID NO:4 having GGPPSASE or unknown activity. The scope of the claims is not

Art Unit: 1652

commensurate with the enablement provided by the disclosure with regard to the extremely large number of constructs broadly encompassed by the claims.

The specification does not teach how to make polypeptides with structures different from SEQ ID NO:4 having GGPPSASE activity. Applicants do not teach which amino acids of SEQ ID NO:4 can be modified without affecting the functional properties of the polypeptide. The specification does teach how to make variants of SEQ ID NO:4 having unknown function. However, the function of a polypeptide cannot be predicted from its structure and the specification does not teach how to use polypeptides with unknown function. Therefore, the breadth of these claims is much larger than the scope enabled by the specification.

While recombinant techniques are available, it is not routine in the art to screen large numbers of amino acids where the expectation of obtaining similar sequences is unpredictable. The amino acid sequence determines the structural and functional properties of an enzyme. Knowledge of which sequences can be altered or removed and still result in similar protein activity is well outside the realm of routine experimentation.

The specification, which places no limitation on the structure of the polypeptides as discussed above, does not support the broad scope of the claims because the specification does not establish: (A) regions of the GGPPSASE structure which may be modified without effecting its activity; (B) the general tolerance of to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (D) the

Art Unit: 1652

specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Therefore, one of ordinary skill would require guidance in order to make polypeptides with structures different from SEQ ID NO:4 having GGPPSASE activity and how to use variant polypeptides of SEQ ID NO:4 having unknown function in a manner reasonable correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 43-76 and 78-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The mere recitation of the name "hGGPPS" is insufficient to convey with clarity that which applicant sees as the invention.

### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Art Unit: 1652

Claims 43 and 69-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Greene et al. (WO 96/21736).

Greene et al. teach a composition comprising a contiguous span of 6-300 amino acids of SEQ ID NO:4, wherein the contiguous span is a truncated polypeptide of SEQ ID NO:4 and wherein the contiguous span includes a Phe residue at position 204, PHE at position 295, a Cys at position 205 and a Pro at position 225 of SEQ ID NO:4 (Figure 3). A truncated polypeptide of SEQ ID NO:4 can be construed as a fragment of SEQ ID NO:4 since a truncated polypeptide is a part broken off or detached from the unmodified polypeptide. Greene et al. teach fragments or portions of the GGPPS polypeptide modified by deletion, and therefore, the fragments of Greene et al. can be construed as enzymatically active fragments consisting of the necessary length of amino acids (pages 9-10).

Greene et al. also teach a composition wherein the polypeptide comprises an amino acid sequence employed for the purification of the polypeptides (pages 10-12). The GGPPS polypeptide of Greene et al. also binds to the human GGPPS or fragments of the human GGPPS. Greene et al. also teach a method of making the GGPPS polypeptides (pages 17-18). Therefore, the teachings of Greene et al. anticipate claims 43 and 69-81.

Claims 43 and 69-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Greene et al. (U.S. Patent 5,786,193).



Art Unit: 1652

Greene et al. teach a composition comprising a contiguous span of 6-300 amino acids of SEQ ID NO:4, wherein the contiguous span is a truncated polypeptide of SEQ ID NO:4 and wherein the contiguous span includes a Phe residue at position 204, PHE at position 295, a Cys at position 205 and a Pro at position 225 of SEQ ID NO:4 (Figure 3). A truncated polypeptide of SEQ ID NO:4 can be construed as a fragment of SEQ ID NO:4 since a truncated polypeptide is a part broken off or detached from the unmodified polypeptide. Greene et al. teach fragments or portions of the GGPPS polypeptide modified by deletion, and therefore, the fragments of Greene et al. can be construed as enzymatically active fragments consisting of the necessary length of amino acids (Columns 6-7).

Greene et al. also teach a composition wherein the polypeptide comprises an amino acid sequence employed for the purification of the polypeptides (Columns 7-8).

The GGPPS polypeptide of Greene et al. also binds to the human GGPPS or fragments of the human GGPPS. Greene et al. also teach a method of making the GGPPS polypeptides (pages 10-11). Therefore, the teachings of Greene et al. anticipate claims 43 and 69-81.

### ***Response to Arguments***

Applicant's arguments filed on March 24, 2003 have been fully considered but they are not persuasive.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 43-68 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants argue the specification provides adequate written description of the polypeptides claimed herein because the specification teaches the structure of the polypeptides, a contiguous span of at least 6 amino acids including the Phe, Phe, Cys and Pro at position 204, 295, 205 and 225, respectively. The examiner disagrees. Claims are drawn to a truncated or fragment or portion of SEQ ID NO:4, but the polypeptide comprising the contiguous amino acids of SEQ ID NO:4 do not have any structural or functional limitations (see previous Office action). The claims are drawn to polypeptide comprising a span of SEQ ID NO:4 and any other amino acids, resulting in a polypeptide having no activity or unknown activity.

Claims 43-68 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the GGPPSASE of SEQ ID NO:4, does not reasonably provide enablement for fragments of SEQ ID NO:4 of unknown structure and function. The specification does not enable any person skilled in the art to which it

Art Unit: 1652

pertains, or with which it is most nearly connected, how to make the invention commensurate in scope with these claims.

Applicants argue the specification teaches the polypeptides claimed herein because the specification teaches the structure of the polypeptides, a contiguous span of at least 6 amino acids including the Phe, Phe, Cys and Pro at position 204, 295, 205 and 225, respectively. Applicants also argue that a skilled artisan would recognize that the polypeptides claimed in the instant invention have structure and function. The examiner disagrees. Claims are drawn to a truncated or fragment or portion of SEQ ID NO:4, but the polypeptide comprising the contiguous amino acids of SEQ ID NO:4 do not have any structural or functional limitations (see previous Office action). The claims are drawn to polypeptide comprising a span of SEQ ID NO:4 and any other amino acids, resulting in a polypeptide having no activity or unknown activity. Therefore, these claims are drawn to a large variable genus of polypeptides having unknown activity or inactive variants with an insufficient limitation on structure. Therefore, many structurally and functionally unrelated polypeptides are encompassed within the scope of these claims, including partial amino acid sequences.

### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 43-68 remain rejected under 35 U.S.C. 102(b) as being anticipated by Greene et al. (WO 96/21736).

Claim 43 has been amended to recite a composition comprising a contiguous span that is a truncated polypeptide of the hGGPPS protein of SEQ ID NO:4. Applicants argue that the reference of Green et al. does not teach a composition comprising a contiguous span that is a truncated polypeptide of SEQ ID NO:4. The examiner disagrees. Green et al. teach fragments and portions of a GGPPS (pages 9-10). A polypeptide that is truncated from the wildtype is one that is a part broken off of the wildtype, detached, or incomplete, which can be construed as a fragment or variant of the wildtype, modified by deletion. Therefore, the teachings of Greene et al. anticipate claims 43-68.

Claims 43-68 remain rejected under 35 U.S.C. 102(e) as being anticipated by Greene et al. (U.S. Patent 5,786,193).

Claim 43 has been amended to recite a composition comprising a contiguous span that is a truncated polypeptide of the hGGPPS protein of SEQ ID NO:4. Applicants argue that the reference of Green et al. does not teach a composition comprising a contiguous span that is a truncated polypeptide of SEQ ID NO:4. The examiner disagrees.

Art Unit: 1652

A truncated polypeptide of SEQ ID NO:4 can be construed as a fragment of SEQ ID NO:4 since a truncated polypeptide is a part broken off or detached from the unmodified polypeptide. Greene et al. teach fragments or portions of the GGPPS polypeptide modified by deletion, and therefore, the fragments of Greene et al. can be construed as enzymatically active fragments consisting of the necessary length of amino acids (Columns 6-7). Therefore, the teachings of Greene et al. anticipate claims 43-68.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1652


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak  
Patent Examiner

May 30, 2003

  
PONNATHAPU ACHUTAMURTHY  
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